Panel Questions for Contact Lens and Care Product Guidance Documents

May 13, 2014

1. Do you believe that FDA's proposed grouping scheme for silicone hydrogel lenses is adequate to mitigate concerns regarding dimensional tolerance and compatibility? If not, what recommendations for modifications would you make?

2. Do you believe that the proposed clinical test matrix for silicone hydrogel lenses is sufficient to address clinical performance issues? If not, what additional testing would you recommend?

3. As a modification to our care product guidance, new care product solutions will be screened for lens preservative uptake incompatibilities using representative lenses per FDA's contact lens grouping system. We propose that the preservative concentration of the solution in the lens case should remain within the manufacturer's specifications after the recommended lens soak time. Incompatible lenses will be listed in the labeling. Please discuss the following:

    a. Should our acceptance criterion account for patient non-compliance (e.g., longer soak times than recommended, solution reuse)?

    b. How should the incompatible lenses be listed in the labeling (e.g., bold text, a unified table)?

    c. Other recommendations?

4. Current microbiological test methods (e.g., ISO 14729) do not take into account "real-world" solution testing parameters in which the lens stored in a case is considered. Please discuss whether you believe the following factors should be incorporated into current preclinical testing:

    a. Soil
    b. Longer soak times
    c. Lens uptake
    d. Any other factors

5. Some RGP lens regimens still recommend the use of water. What alternatives would you recommend to replace water (e.g., preserved saline, unpreserved saline etc.)?